

### **REMARKS**

Applicants respectfully request reconsideration of the present case in view of the following remarks. Claims 1-33 and 45-49 are currently pending.

### **Objections to the Specification**

The Examiner has indicated that the Amendment filed July 2, 2004 remains objected to under 35 U.S.C. 132(a) for introducing new matter. Applicants respectfully request withdrawal of this objection since the language was deleted from the Specification in the Amendment filed February 2, 2008.

### **Rejections under 35 U.S.C. § 103(a)**

Claims 1-7, 15-21 and 45-49 were rejected under 35 U.S.C. § 103(a) as unpatentable over Schiraldi et al. (US Re. 33,093) in view of Tarvainen et al. (Predicting Plasticization Efficiency from Three-Dimensional Molecular Structure of a Polymer Plasticizer, 2001). Applicants respectfully traverse this rejection.

Specifically, the Examiner asserts that Schiraldi teaches a medicament-containing extruded thermoplastic film that includes 20-95% hydroxypropylcellulose, 5-60% ethylene oxide homopolymer and 2-10% plasticizer. The Examiner acknowledges that Schiraldi does not teach the claimed fatty alcohol component and attempts to remedy this deficiency by combining Schiraldi with Tarvainen, asserting that Tarvainen teaches the use of cetyl alcohol and stearyl alcohol as plasticizers in polymeric films. Applicants respectfully disagree with the asserted teachings of Tarvainen and the combination with Schiraldi.

In contrast to the Examiner's assertion, Tarvainen does not teach the use of cetyl alcohol and stearyl alcohol as plasticizers in polymeric films. Tarvainen tested 24 compounds, including cetyl alcohol and stearyl alcohol, for their plasticization efficiency ( $\beta$ ) (See, Tarvainen, Abstract). A decrease in glass transition temperature ( $T_g$ ) of the film was used as an indicator of plasticization efficiency (page 1760, col. 2): poor plasticizers had a decrease in  $T_g$  of less than 30°C (page 1763, col. 2); and compounds that raise the glass transition temperature ( $T_g$ ) were

considered antiplasticizing (page 1763, col. 1). The plasticizing efficiency ( $\beta$ ) of the 24 tested compounds is shown in Table 1. Cetyl alcohol had a plasticizing efficiency of  $0 \pm 0$ ; and stearyl alcohol had a plasticizing efficiency of  $13 \pm 3$ . Thus, according to Tarvainen, cetyl alcohol is a poor plasticizer and stearyl alcohol is an antiplasticizing compound.

In determining whether an invention is obvious, the prior art must be considered *in its entirety*, including disclosures that teach away from the claims. See, MPEP § 2141.02. “A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference or would be led in a direction divergent from the path that was taken by the applicant.” *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). In fact, proceeding contrary to accepted wisdom in the art is evidence of nonobviousness. *In re Hedges*, 783 F.2d 1038, 228 USPQ 685 (Fed. Cir. 1986)

When the teachings of Tarvainen are taken as a whole, it is clear that Tarvainen teaches away from the use of cetyl and stearyl alcohol as plasticizers. Therefore, Tarvainen cannot be combined with Schiraldi to render the claimed thermoplastic film, which includes both hydroxypropyl cellulose and a fatty alcohol component obvious. Applicants therefore respectfully request withdrawal of this rejection.

Claims 1, 7-14 and 22-33 were newly rejected under 35 U.S.C. § 103(a) as being unpatentable over Schiraldi et al. (US Re. 33,093) in view of Tarvainen et al. (Predicting Plasticization Efficiency from Three-Dimensional Molecular Structure of a Polymer Plasticizer, 2001, and in further view of Myers et al. (US 2007/0122455) evidenced by Engleson (US 7,153,531). Applicants respectfully traverse this rejection.

As discussed above, the combination of Schiraldi and Tarvainen is improper and does not render the claimed invention obvious. Myers was cited by the Examiner for its teachings of bulking agents, flavorants and sweeteners for use in rapid-dissolving water-soluble films and does not remedy the deficiencies of the primary references. Similarly, Engleson was cited for the disclosure of dextrose and other carbohydrates as bulking agents in pharmaceutical or food compositions and likewise does not remedy the deficiencies of the primary references. Applicants therefore request withdrawal of this rejection.

**Summary**

In view of the remarks above, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

August 8, 2008  
Date

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